UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION IX
75 Hawthorne Street
San Francisco, CA 94105

Date: AUG 17 2015

CERTIFIED MAIL NO. 7003 3110 0006 1998 6200
RETURN RECEIPT REQUESTED

Mr. Mark Harvey
Vice President, Corporate Operations
Inmar EXP Healthcare
48021 Warm Springs Blvd.
Fremont, CA 94539

RE: **Request for Information In re: EXP Pharmaceutical Services Corp. (EXP)**
EPA Identification Number: CAR000149906

Dear Mr. Harvey:

The United States Environmental Protection Agency (EPA), Region 9 hereby requests additional information following the July 7, 2015 compliance evaluation inspection conducted at the EXP Pharmaceutical Services Corp. (EXP or Facility) facility located at 48021 Warm Springs Blvd, Fremont, CA 94539, EPA Identification Number CAR000149906. The information being requested will supplement observations made by the EPA inspection team.

Pursuant to EPA's authority under Section 3007(a) of the Resource Conservation and Recovery Act (RCRA) [42 U.S.C. § 6927(a)], EXP is required to submit the information and documents listed in Attachment I of this letter using the instructions included in Attachment II. Also, complete and submit the certification included in Attachment III.

Failure to respond fully and truthfully may result in enforcement action by EPA pursuant to Section 3008(g) of RCRA (42 U.S.C. § 6928(g)). These statutory provisions authorize EPA to seek the imposition of penalties of up to $37,500 per day of noncompliance. Please be further advised that provision of false, fictitious or fraudulent statements or representations may subject you to criminal penalties under 18 U.S.C. § 1001. The information you provide may be used by EPA in administrative, civil or criminal proceedings.

This request for information is not subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act because it is not a collection of information within the meaning of 44 U.S.C. §§ 3502(3), 3507, and 3512. *See*, *also*, 5 C.F.R. §§ 1320.3(c), 1320.5, and 1320.6(a). Furthermore, it is exempt from OMB review under the Paperwork Reduction Act because it is part of

an investigation of a specific individual or entity. 44 U.S.C. § 3518(c)(1); 5 C.F.R. § 1320.4.

Your response to this request must be made by letter, signed by a duly authorized official, and submitted to the EPA within thirty (30) calendar days from the date of your receipt of this letter. Please address the submittal to:

Christopher Rollins
Mailcode: ENF-2-2
Waste and Chemical Section
Enforcement Division
U.S. Environmental Protection Agency
75 Hawthorne Street
San Francisco, CA 94105
e-mail: rollins.christopher@epa.gov

In lieu of submitting the requested response by mail, EXP may submit the response as portable document files via electronic mail, unless the response contains Confidential Business Information (CBI).

You may have been provided during the inspection with a Small Business Regulatory Enforcement and Fairness Act (SBREFA) Information Sheet. If not, please see http://www.epa.gov/compliance/resources/publications/incentives/smallbusiness/smallbusresources.pdf. The Information Sheet is designed to provide information on compliance assistance and inform small businesses of their rights to comment to the SBREFA Ombudsman concerning EPA enforcement activities. Be aware that SBREFA does not eliminate your responsibilities to respond to this letter within the allowed time nor does it create any new rights or defenses under the law.

If you have any questions regarding this letter, please contact Christopher Rollins at (415) 947-4166.

Sincerely,

Douglas K. McDaniel
Chief, Waste and Chemical Section
Enforcement Division

Enclosures

cc:

Kristine Green, DTSC; kristine.green@dtsc.ca.gov
Asha Arora, DTSC; aarora@dtsc.ca.gov
Jacqueline Nomany, Fremont Fire Department; jnomany@fremont.gov

ATTACHMENT I

Therefore, pursuant to EPA's authority under Section 3007(a) of RCRA, EXP Pharmaceutical Services Corp. (EXP or facility) is requested to submit to EPA the following information:

1. Please provide a detailed written description of all the *materials* (i.e., pharmaceuticals[1], electronic devices, laboratory chemicals (products and wastes), and batteries) received and managed at EXP's Fremont location.

2. Please provide EPA with a comprehensive list of all EXP's customers located in Arizona, California, Hawaii, Nevada, Guam and the Commonwealth of the Northern Marianas Islands (Region 9 Area) that have shipped *materials* to EXP's Fremont location from July 7, 2012 – July 7, 2015. Please identify the customers by company name, address, and materials shipped.

3. Please list the names of all the common carriers EXP's customers use to ship *materials* from the customer's location to the EXP facility located in Fremont, CA.

4. Please provide EPA with copies of EXP's acceptance policy and the Standard Operating Procedures (SOP) for managing *materials* delivered and/or mailed to the Fremont facility. Please explain the process for managing non-conforming *materials* received by the facility for processing.

5. Please provide EPA with a list of customers that have transported *materials* directly to the EXP facility. For the customers that transported these *materials* directly to EXP, please provide EPA with a list of these specific customers by company name, address, delivery date and *materials* received by EXP from July 7, 2014 to July 7, 2015 to be processed.

6. If there are any subcontractors or other companies which operate within the facility, provide EPA with the name(s) of the subcontractor(s) or company(ies), a description of the work performed by each contractor or company, and the name and title of the primary subcontractor/company contact.

7. Please provide a detailed written description on how *materials*, by category (i.e., pharmaceuticals, electronic devices, laboratory chemicals, and batteries) are tracked through the facility. In the written description please identify if the customer name, customer number, or other information is used to track *materials* internally from the generator to the off-site disposal facility. If a form(s) is used to track the *materials*, please provide EPA with the name(s)/number(s) of the form(s) and a copy of the completed form(s) generated by EXP from July 7, 2014 – July 7, 2015.

8. Provide a detailed written description of the criteria (e.g., pharmaceutical weights and number of containers) EXP uses to bill its customers for *materials* shipped to the facility for processing.

9. Confirm that EXP's Fremont location serves as the corporate office and main processing center for *materials* shipped to the facility for processing. Please provide EPA with the complete address of

[1] Pharmaceuticals include controlled substances regulated by the Drug Enforcement Administration.

any other EXP location that also receives or processes *materials* on-site.

10. Provide EPA with the average time EXP takes to process materials received at the Shipping and Receiving area.

11. Please provide a detailed written description of the Cactus Smart Sink device (device) that is advertised on the facility's website. Include in the written description if EXP owns or just markets the device. If EXP only markets the device, please provide EPA with contact information for the device manufacturer.

12. Provide a detailed written description of the processes, including any chemical reactions the Cactus Smart Sink device utilizes to render pharmaceuticals unrecoverable and unusable in both solid and liquid waste streams.

13. Provide copies of EXPs policies and procedures to ensure that no RCRA regulated wastes are placed and/or disposed of in the device.

14. Please provide EPA with a list of all Cactus Smart Sink customers located in the Region 9 Area that have purchased and/or shipped waste cartridges accumulated and/or generated from the device(s) to EXP for disposal from July 7, 2012 – July 7, 2015. Please identify the customers by company name and address.

15. Please provide the name(s), title(s) and location(s) of those individual EXP representatives that prepare Cactus Smart Sink customer's waste shipments (in the Region 9 Area) and documents on behalf of the customer.

16. During EPA's inspection, several small containers were observed in EXP's Processing Department marked with the words "Pending." Please provide a written description of what EXP means by the term "Pending." If the term is included in EXP materials management policies or procedures, provide EPA with the reference(s) where this term is defined.

17. Please provide EPA with signed final copies (if applicable) of the following ten EXP outgoing manifests and their related disposal paperwork; 1) 006842981 FLE, 2) 008100106 FLE; 3) 008100108 FLE; 4) 008335845 FLE; 5) 008335846 FLE; 6) 008335530 FLE; 7) 008398461 FLE; 8) 008398462 FLE; 9) 008844290 FLE; 10) 008844291 FLE.

18. During EPA's inspection, a representative of EXP's parent company Inmar stated that an internal review of EXP's shipment activities determined that some of the RCRA hazardous waste manifests listed above (Item 17) had not been submitted to and/or filed with the Department of Toxic Substances Control (DTSC). Please provide the dates when EXP and/or Inmar conducted this manifest review. Please provide EPA with a detailed written discussion of other issues that were identified by Inmar during the manifest review. Please provide EPA with documentation that the manifest copies have been submitted to DTSC or other state agencies, as required. Additionally, provide EPA with any manifest exception reports that were prepared by EXP or its representatives as result of Inmar's manifest review.

19. EXP during the inspection stated that all materials received by the facility are disposed of at an off-site permitted location. Please confirm that none of the *materials* are reused, donated or recycled. If any of the listed *materials* are reused, donated or recycled, please provide EPA with a detailed list of the companies' names, addresses, contacts and phone numbers of the facilities that EXP sent *materials* to for one or more of these purposes.

20. Provide EPA with the percentage of total pharmaceuticals received at EXP that are shipped for incineration versus those that are reused, donated and/or recycled. Of the total percentage of *materials* received by the facility, please provide EPA with the total amount of *materials* that are sent for direct incineration by EXP versus those that are shipped back to the manufacturer for incineration.

21. Provide EPA with a list of all facilities by waste type (e.g., RCRA hazardous waste, discarded or expired pharmaceuticals, California hazardous wastes), including name and complete address, that EXP utilizes to treat (e.g., incineration) or dispose of *materials* and other wastes processed at the facility.

22. Please provide EPA with a detailed written explanation on the pharmaceutical manufacturer's reverse distributor process. Please also explain how EXP receives credit back for certain pharmaceuticals received by the facility's customers.

23. Please describe where exactly in EXP's process the facility decides when *materials* become waste. Additionally, provide EPA with the names and titles of the EXP personnel that are specifically responsible for deciding when *materials* become waste.

24. Provide EPA with copy of the SOP or other written policies or procedures EXP had in effect at the time of EPA's inspection for managing RCRA hazardous waste (D-wastes [e.g., D003], F-Listed, P-list and U-listed) and other wastes (e.g., universal wastes, California hazardous wastes) within EXP's less than 90-Day Hazardous Waste Storage Area (HWSA).

25. Provide EPA with a written description of the policies and/or procedures EXP has established since EPA's inspection to ensure that hazardous, non-hazardous, and universal wastes are being managed in accordance with federal, state and local requirements on-site.

26. EXP receives devices that contain various types of batteries (e.g., lithium). Please provide a copy(ies) of any permits issued by DTSC, Alameda County and/or City of Fremont, California for receiving and accumulating discarded or spent batteries contained in devices or shipped separately to the facility. Additionally, provide EPA with any copies of notifications to any of the agencies previously listed where EXP notified the agencies that the facility was handling discarded or spent batteries that were shipped to the facility. Also please provide any notifications made to EPA regarding the handling of discarded or spent batteries.

27. Prior to July 7, 2015, for lithium batteries shipped to the facility either separately or contained in devices, please provide a written detailed description on how EXP insured that the lithium batteries

were shipped safely to the facility and in accordance with federal Department of Transportation (DOT) requirements. Please provide the name(s) and title(s) of the person(s) responsible for insuring that the lithium batteries were shipped safely to facility and in accordance with DOT requirements. Please provide a copy of EXP's current battery management policies and procedures.

28. Provide a list of customers from July 7, 2012 to July 7, 2015 that have shipped batteries directly to the facility or contained in a device. Include in list the complete company name and address for each customer who shipped batteries or battery containing equipment to EXP. Additionally, include a description and quantity of devices and/or the type of batteries that were shipped to the facility.

29. Provide a complete list of RCRA hazardous waste streams specifically generated by EXP activities on-site and a complete list of RCRA hazardous waste streams generated by EXP's customers that are directly managed by EXP as RCRA hazardous wastes.

30. EXP temporarily stores for customers pharmaceuticals until the stored pharmaceuticals meet the expiration requirements of the manufacturer. Please provide a written detail description of the process and provide copies of any SOPs or other policies or procedures EXP had established at the time of EPA's inspection that describes this process. Please confirm that EXP is identified as the generator on the shipping documents of the stored pharmaceuticals sent off-site for disposal or incineration.

31. Please provide the names and addresses of the pharmaceutical manufacturers that EXP has entered into contractual agreements with regarding the receipt, storage and management of pharmaceuticals on-site. Please provide EPA with copies of each contractual agreements between EXP and the manufacturer.

32. If any of the temporarily stored pharmaceuticals are returned to the manufacturer, explain the circumstance(s) that requires EXP to return the pharmaceuticals back to the manufacturer.

33. During the exit briefing, EXP representatives stated that the pharmaceuticals have an "intrinsic value" during this period the pharmaceuticals are being temporarily stored. Please provide a detailed explanation what the EXP representative meant by the term "intrinsic value."

34. The table below identifies facilities that EPA requests EXP provide all shipping documents of *materials* and/or Cactus Smart Sink wastes shipped by these facilities from July 7, 2014 to July 7, 2015 to EXP for processing:

CAD079605366	LA COUNTY, HARBOR - UCLA MEDICAL CENTER	1000 W CARSON ST	TORRANCE	CA
AZD982328387	ST JOSEPHS HOSPITAL & MED CTR	350 W THOMAS RD	PHOENIX	AZ

HIR000132001	HILO MEDICAL CENTER	1190 WAIANUENUE AVENUE	HILO	HI
CAD095615027	LAC & USC MEDICAL CENTER	1200 N STATE ST ROOM 501	LOS ANGELES	CA
CA0000844589	SUTTER DAVIS HOSPITAL	2000 SUTTER PL	DAVIS	CA
CA1360090244	VETERANS ADMIN MED CTR	2615 E CLINTON AVE	FRESNO	CA
AZR000043000	PHS/ IHS SELLS INDIAN HOSPITAL	HWY 86 AND TOPAWA RD	SELLS	AZ
AZD108149881	SAINT JOSEPH'S HOSPITAL	350 N WILMOT RD	TUCSON	AZ
CAD098625437	LOS ANGELES DOCTORS HOSPITAL	2231 SOUTH WESTERN AVE	LOS ANGELES	CA
HI0000272906	LONGS DRUG STORE NO 9228	1330 PALI HWY	HONOLULU	HI
HIR000142117	QUEEN'S MEDICAL CENTER - WEST OAHU	91-2141 FORT WEAVER ROAD	EWA BEACH	HI
NVR000083964	MOUNTAINVIEW HOSPITAL	3100 N TENAYA WAY	LAS VEGAS	NV
CAD082903642	KAISER SANTA TERESA MEDICAL CENTER	250 HOSPITAL PARKWAY	SAN JOSE	CA
NVD981578990	RENOWN REGIONAL MEDICAL CENTER	1155 MILL ST	RENO	NV
CAD076074137	GOOD SAMARITAN HOSPITAL OF ORANGE CTY	1025 S ANAHEIM BLVD	ANAHEIM	CA
CAL000309829	USC/NORRIS CANCER HOSPITAL	1441 EAST LAKE AVENUE	LOS ANGELES	CA
HIR000135376	STRAUB CLINIC AND HOSPITAL	888 SOUTH KING STREET	HONOLULU	HI
NNR000034710	SAGE MEMORIAL HOSPITAL	HWY 264	GANADO	AZ
AZ0360010342	VETERANS AFFAIRS MEDICAL CENTER	3601 S 6TH AVE	TUCSON	AZ

CAR000252817	SUTTER HEALTH SACRAMENTO SIERRA REGION DBA SUTTER AMADOR HOSPITAL	200 MISSION BLVD	JACKSON	CA
CAD983581026	USC UNIVERSITY HOSPITAL	1500 SAN PABLO STREET	LOS ANGELES	CA

ATTACHMENT II
INSTRUCTIONS

In responding to this Request for Information, apply the following instructions and definitions:

1. Answer Every Question Completely. A separate response must be made to each of the questions set forth in this Information Request. For each question contained in this letter, if information responsive to this Information Request is not in your possession, custody, or control, please identify the person(s) from whom such information may be obtained.

2. Number Each Answer. When answering the questions in Attachment I, please precede each answer with the corresponding number of the question and subpart to which it responds.

3. Number Each Document. For each document produced in response to this Information Request, indicate on the document, or in some other reasonable manner, the number of the question to which it corresponds.

4. Provide the Best Information Available. Provide responses to the best of Respondent's ability, even if the information sought was never put down in writing or if the written documents are no longer available. You should seek out responsive information from current and former employees/agents, if necessary. If you are unable to answer a request in a detailed and complete manner or if you are unable to provide any of the information or documents requested, indicate the reason for your inability to do so. If you have reason to believe that there is an individual who may be able to provide more detail or documentation in response to any request, state that person's name and last known address and phone number and the reasons for your belief.

   If anything is deleted from a document produced in response to this Request for Information, state the reason for and the subject matter of the deletion. If a document/information is requested but is not available, state the reason for its unavailability. In addition, identify any such document by author, date, subject matter, number of pages, and all recipients and their addresses.

5. Identify Sources of Answer. For each question, identify all the persons and documents that you relied on in producing your answer.

6. Continuing Obligation to Provide/Correct Information. If additional information or documents responsive to this Request become known or available to you after you respond to this Request, EPA hereby requests that you supplement your response to EPA.

7. Scope of Request. The scope of this request includes all information and documents independently developed or obtained by research on the part of your company, its attorneys, consultants or any of their agents, consultants or employees.

8. Have an Authorized Person Sign the Response and Certification (Attachment III). The signatory must be an officer or agent who is authorized to respond on behalf of the company or facility.

9. **Confidential Information.** The information requested herein must be provided even though you may contend that it includes confidential information or trade secrets. You may assert a confidentiality claim covering part or all of the information requested, pursuant to Section 3007(b) of RCRA, 42 U.S.C. § 6927(b), and 40 C.F. R. § 2.203(b).

If you make a claim of confidentiality for any of the information you submit to EPA, you must prove that claim. For each document or response you claim confidential, you must separately address the following points:

i. clearly identify the portions of the information alleged to be entitled to confidential treatment;
ii. the period of time for which confidential treatment is desired (e.g., until a certain date, until the occurrence of a specific event, or permanently);
iii. measures taken by you to guard against the undesired disclosure of the information to others;
iv. the extent to which the information has been disclosed to others, and the precautions taken in connection therewith;
v. pertinent confidentiality determinations, if any, by EPA or other federal agencies, and a copy of any such determinations or reference to them, if available; and
vi. whether you assert that disclosure of the information would likely result in substantial harmful effects on your business' competitive position, and if so, what those harmful effects would be, why they should be viewed as substantial, and an explanation of the causal relationship between disclosure and such harmful effects.

To make a confidentiality claim, please stamp, or type, confidential on all confidential responses and any related confidential documents. Confidential portions of otherwise non-confidential documents should be clearly identified. You should indicate the date, if any, after which the information need no longer be treated as confidential. Please submit your response so that all non-confidential information, including any redacted versions of documents are in one envelope and all materials for which you desire confidential treatment are in another envelope that is clearly marked confidential.

All confidentiality claims are subject to EPA verification. It is important that you satisfactorily show that you have taken reasonable measures to protect the confidentiality of the information and that you intend to continue to do so, and that it is not and has not been obtainable by legitimate means without your consent. If no such claim accompanies the information when it is received by EPA, then it may be made available to the public by EPA without further notice to you.

If the EPA determines that the information so designated meets the criteria set forth in 40 C.F.R. § 2.208, the information will be disclosed only to the extent, and by means of the procedures specified in 40 C.F.R. Part 2, Subpart B.

ATTACHMENT III
CERTIFICATION OF ANSWERS TO RESPONSES TO REQUEST FOR INFORMATION

I certify under penalty of law that I have personally examined and am familiar with the information submitted in this document (response to EPA Request for Information) and all documents submitted herewith, that the submitted information is true, accurate and complete, and that all documents submitted herewith are complete and authentic, unless otherwise indicated. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

_____

NAME (print or type)

_____

TITLE (print or type)

_____

SIGNATURE

_____

DATE